

Remarks

This is in response to the final Office Action dated June 10, 2009 in the above-identified patent application.

I. Status of the Claims.

- 5 Claims 1, 3-4, 6-47 and 49-52 were pending for purposes of the instant Office Action. Claims 2, 5, and 48 were previously canceled without prejudice. Claims 1, 3-4, 6-47 and 49-52 are canceled herein, and new claims 53-79 replace those canceled claims, as provided in the Listing of Claims, above.

- 10 Certain different embodiments encompassed by original claim 1 are now recited in separate new claims 53-55 for purposes of clarification. The subject matter of original claim 29 is now presented in new claim 56.

- 15 Because the newly presented claims are re-worded and based substantially on the original claims, or include minor clarifications that are expressly supported in the specification (including the drawings and the text accompanying the drawings), it is respectfully submitted that no new matter is presented. Specifically, the recitation of the breaking segment which allows breaking the tablet through the tablet without substantial "consequent breakage of the first segment" is provided in the specification as filed, at page 6, lines 25-28. Reconsideration is respectfully requested.

II. Summary of Interview

- 20 Applicants, and applicants' attorney, gratefully acknowledge the Examiner's granting of the telephonic interview conducted on September 8, 2009. The attendance of SPE Sharmila Landau is also greatly appreciated. Attending for applicants were: applicants' attorney Ted Whitlock, assignee President, Rob Goldfarb, and co-inventor Allan Kaplan. During the interview, applicants were provided the opportunity to identify the proposed direction of the claims and to
- 25 discuss the issues raised in the pending Office Action. Applicants were advised of specific claim language concerns (e.g., the use of "comprising" as the transitional phrase in original claim 1, and prior art issues as the claims were previously drafted.) No agreement was reached.

III. Rejection under 35 USC §112

Original claims 11 and 12 were rejected under 35 USC §112, second paragraph, as being indefinite. The rejection concerned an issue of proper antecedent basis. Original claims 11 and 12 have been canceled by this amendment, which makes the indefiniteness rejection moot. Applicants believe the newly proposed claims contain proper antecedent basis for each of the recited terms. Accordingly, applicants respectfully request withdrawal of the rejection.

IV. Claim Rejections under 35 USC §103.

Claims 1, 3-4, 6-10, 13-34, 39-47, and 49-50 stand rejected under 35 USC §103(a) as being unpatentable over Lieberman (Pharmaceutical Dosage Forms – tablets, 1990) in view of Geller (US Pat. No. 3,927,194). This rejection is respectfully traversed.

Applicants respectfully submit that the cited references simply fail to teach or suggest, and make obvious, the invention as now claimed. The Examiner's attention is respectfully directed to the newly presented claims, especially independent claims 53-56. These claims define the primary embodiments of the dosage forms (originally provided in claims 1 and 29), namely:

- (a) a deeply scored, compressed, segmented tablet having an inactive, immediate release composition forming an outer segment of the dosage form (claim 53);
- (b) a compressed segmented dosage form which is taller-than-wide and has an inactive, immediate release segment between its two (or more) active segments that are compatible with one another (claim 54);
- (c) a compressed segmented dosage form which is taller-than-wide, has an inactive inner segment between two (or more) active segments and either i) lacks a semi-permeable membrane coating, ii) lacks an osmotically active component to effect intrinsic altered release, or iii) lacks a drug over-coating (claim 55); and
- (d) a taller-than-wide dosage form having an inactive middle segment and expressed in terms of its specific and unique layer configuration (claim 56).

None of these structural configurations of the dosage forms recited in any of claims 53-56 are taught or suggested in Lieberman or Geller.

First, regarding new claim 53, nothing in Lieberman or Geller teaches or suggests providing an inactive, immediate release segment as an outer layer of a dosage form. Lieberman is clearly cited for its teaching of an inactive layer disposed *between* two active layers. Geller is then cited for its description of a deep score which may be formed in a tablet. However, it is the claimed
5 element of the inactive outer segment, as expressly recited in claim 53, which is unique and unobvious from the cited references and distinguishes the subject dosage forms from any of those described in Lieberman or Geller. Accordingly, providing a score from Geller in a tablet of Lieberman does not teach or suggest, and would not have made obvious, the unique and advantageous dosage form having an inactive outer segment, as provided in claim 53.

10 Further, this outer inactive segment of the subject invention advantageously serves as a breaking segment, allowing breakage through that segment only, and avoiding substantial breakage of the active segments. Such advantage cannot be provided by any tablet configured as described in Lieberman or Geller. Lieberman is concerned with providing an inactive *middle* layer in a tablet, which serves to separate two active layers that are incompatible with one another as they are
15 present in the final dosage form. Therefore, Lieberman is deficient in its teaching of a layered tablet which has an inactive layer as an outer layer and which serves as a breaking segment to allow breaking of the tablet without breaking the active segments. Geller provides no teaching or suggestion which would cure this deficiency of Lieberman.

With regard to claim 54, which includes a middle inactive layer, there is nothing in Lieberman,
20 or anywhere in the prior art to applicants' knowledge, that teaches or suggests adding a layer or segment between two compatible compositions, as claim 54 expressly recites. One reason for the lack of such teaching or suggestion in the prior art is because it was previously understood that providing an additional layer to separate two compatible compositions was superfluous, and was not desired in view of the increased manufacturing time and costs. The previous Office
25 Action of record admits that "Lieberman teaches ... layered dosage forms [that] have the advantage of being able to separate two *incompatible* substances with an inert barrier or ... [that] can be used *to modify the release profile*." However, as claim 54 expressly recites, the claimed dosage form provides an inner layer separating two *compatible* compositions, a configuration that applicants believe would have been unobvious from the cited references.

Moreover, the inactive, inner layer of the subject tablets is not specifically provided to affect the release profile of the tablet or the individual layers; rather, the inactive inner layer advantageously and unobviously serves as a breaking region in the tablets. Again, this breaking segment allows division of the tablet by breaking only through the inactive inner layer, without breaking either of the adjacent active layers or segments. Such advantage was clearly not mentioned or contemplated by Lieberman because Lieberman described only the inclusion of a third (inactive) layer for the purpose of keeping apart two incompatible layers. Applicants therefore respectfully submit that it would have been unobvious for a person of ordinary skill in the art to add the “superfluous” inactive layer in a tablet which was not believed to need an inactive layer since the active layers are compatible with one another.

In addition, claim 54 recites that the dosage form has a height greater than its width. The state of the art at the time of Lieberman or Geller did not envision tablets having this taller-than-wide configuration. Accordingly, Lieberman or Geller cannot be said to teach or suggest a tablet as claimed in claim 54. Lieberman and Geller are therefore deficient in their teaching of a tablet having an inactive layer between two active layers compatible with one another, and having its height greater than its width. Thus, neither Lieberman nor Geller can cure the deficiencies of the other and, accordingly, would not have made obvious the claimed invention, even if combined.

The unique taller-than-wide aspect of the subject invention is also expressly provided for dosage forms claimed in independent claims 55 and 56. Applicants therefore respectfully traverse any applicability of the Lieberman or Geller references to the dosage forms recited in these claims.

Applicants respectfully submit that there is no reason provided within the prior art to modify Lieberman with the Geller score technique. As stated, Lieberman is restricted to wider-than-tall tablets having a middle layer provided solely to separate incompatible layers, and Geller is concerned with making a single layer tablet with an active ingredient. Thus, neither of the cited references suggest a two or three layered tablet that is taller-than-wide, as claimed. Also, neither Lieberman nor Geller, alone or in combination, suggest the concept of a tablet wherein all or most of the breakage occurs in an inert layer, which greatly increases the stability and integrity of the tablet during manufacture and shipping, as well as the accuracy of the tablet splitting as

compared to the accuracy of splitting a tablet by merely using a deep score through a homogeneous, non-layered tablet, as in Geller.

Neither the specific concept of the present invention, as delineated by the unique structural elements expressly recited in the claims, nor the unique advantages of the subject dosage forms is found in either of the cited references. The advantageous tablet stability and accurate breakage capabilities of the subject dosage forms support the unobviousness of the claimed invention as compared to the differing concepts set forth in Lieberman and Geller. Each of the cited references describes tablet configurations that are *structurally* different than the claimed invention and, further, that are provided for completely different purposes.

The Office Action points to Lieberman's description of a "sandwiched" three-layer tablet. However, the "sandwich" configuration of Lieberman clearly emphasizes the distinction of such configuration from the "taller-than-wide" configurations of the subject invention of claims 54-56. Lieberman makes the point of stating that the intermediate layer should be a thin layer. Specifically, Lieberman clearly recites that, in a multilayer tablet containing incompatible actives, e.g., an analgesic-antipyretic decongestant consisting of aspirin and phenylpropanolamine, "[a] thin layer of placebo is placed between [the active layers] to negate the chemical incompatibility of the active ingredients" (emphasis supplied). See, H.A. Lieberman, and L. Lachman (Eds.), *Pharmaceutical Dosage Forms. Vol. 1*, Marcel Dekker, Inc., New York, NY (1989), 217-224 at p. 219.

The thin inactive middle layer of Lieberman serves only to provide a barrier between the incompatible actives and would suggest to a person of ordinary skill in the art that compatible actives do not need a separating layer between them. Thus, providing any inactive layer between two compatible active segments as claimed would not have been obvious to a person of ordinary skill in the art from the teaching of Lieberman. Further, modification of the contents of the different layers to provide compatible actives in the top and bottom layers of a tablet would have led a person of ordinary skill in the art to forgo the inactive middle layer because it would have been superfluous in accordance with the teachings of Lieberman. Only the subject invention describes a tablet having the unique and advantageous element of an inactive layer between two compatible active layers.

The Office Action further suggests that the subject invention would have been obvious based on Lieberman teaching varied thicknesses of the layers. Again, however, Lieberman teaches or suggests only that an inactive middle layer should be provided between two incompatible active

layers as in claim 54. The embodiment of the subject invention comprising an inactive layer between two compatible active layers, regardless of the thickness of the layers would not have been obvious in view of Lieberman. Moreover, although Lieberman may teach that the thickness of the active layers can be varied, Lieberman clearly limits the thickness of the middle inactive barrier layer to a “thin” layer. Therefore, Lieberman does not teach varied thicknesses of all layers of the tablet – only the active layers. This is clearly different than the subject invention which provides a relatively thick inactive middle layer.

It should be further noted that, regardless of varying thicknesses of the *active* layers that may be available from Lieberman, the description of a thin, inactive middle layer as required by Lieberman still results in a tablet that is broken through all three layers when divided. By contrast, a taller-than-wide tablet of the subject invention allows for breaking through only the middle layer, leaving the active segments intact after breaking.

In contrast to the assertion in the instant Action that one of ordinary skill in the art would have been motivated to have a deeper score to facilitate breakage of the tablet, this assertion still fails to provide any nexus between the deeper score that *could* be provided from Geller, and the specific structure of the dosage form that is currently claimed. More specifically, Geller may suggest placing a deeper score in a tablet of Lieberman, but neither Geller nor Lieberman describe the claimed dosage forms in which such score could be placed. It should be clarified that applicants do not rely on the depth of the score in the tablets as the distinctive aspect of the invention for differentiating its tablets from those of Lieberman and/or Geller; rather, the distinctive and unobvious aspect of the claimed invention lies in the layering configurations (inactive outer segment or certain taller-than-wide tablets having three or more layers) and therefore the structure of the tablets, themselves.

In further response to the following issues relating to applicants’ arguments in the previous Reply, applicants clarify as follows:

- 1) “nowhere in the instant claims does applicant specifically require that an inactive layer be adjacent to an active layer.”

The requirement of an inactive layer being adjacent to an active layer is expressly recited in claim 53 as “an outer segment that lacks a pharmacologically effective quantity of any drug adjacent to a segment comprising a pharmacologically effective quantity of any drug.”

2) “Lieberman teaches at least (c) in claim 8 and at least (b) in claim 22.”

The currently presented claim 54 (as previously recited in original claim 8(c)) recites that the middle segment between compatible, active segments is inactive. It is reiterated that Lieberman does not teach or suggest a middle inactive segment disposed between two compatible active segments. Further, applicants maintain that the recitation of a middle layer having a height of at least 0.5 mm (previously in original claim 22 and now recited in claim 70) is not taught or suggested by the teaching of a “thin” layer between incompatible active layers of Lieberman.

The prior rejection of claims 35-38 and 51-52 under 35 USC §103(a) as being unpatentable over Lieberman in view of Geller, and in view of Lofroth, et al., (US Pat. No. 6,827,947) has been maintained in the instant Action. The reference of Lofroth is cited for its description of coated tablets and sachets (original claims 35-37) and for its disclosure of the treatment of certain medical conditions, including the use of metoprolol (original claims 38 and 51-52). Subject matter recited in original claims 35-37 is now presented in new claims 76-79. Subject matter of original claims 38 and 51-52 is canceled from the current claims; therefore, the rejection as it applies to the canceled subject matter is moot.

Applicants respectfully submit that the applicability of Lofroth is limited and is useful only to show disclosure of elements recited in dependent claims 76-79. Lofroth therefore clearly fails to cure the defects of Lieberman or Geller as applied to the newly presented independent claims 53 and 56, and thus cannot provide further support for an obviousness rejection. Accordingly, applicants respectfully submit that this rejection fails, as the claimed invention would not have been obvious in view of any one of Lieberman, Geller, or Lofroth taken separately or together. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 35-38 and 51-52 under 35 USC §103(a).

Finally, claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/598,344.

Because the instant claims have been amended, and the claims of either the instant application

or the cited '344 application have not yet been allowed, applicants respectfully submit that the issue of obviousness-type double patenting, and the submission of a terminal disclaimer to overcome the obviousness-type double patenting rejection, will be considered upon indication of allowability for the claims.

- 5 In view of the above amendments to the claims and the accompanying Remarks, applicants believe that the pending claims, as amended, are in condition for allowance and respectfully request issuance of the Notice of Allowance forthwith.

Applicants invite the Examiner to contact the undersigned at the address and/or phone number provided below if clarification or additional information is needed on any of these matters.

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